

Rapid development of a portable negative pressure procedural tent

Dear Editor,

Healthcare workers face unprecedented risks during the COVID-19 pandemic. The SARS-CoV-2 virus is highly contagious¹ and is transmitted via respiratory droplets, with evidence suggesting the possibility of airborne transmission.^{2,3} Air and surface contamination has been demonstrated 4 m from the source.⁴ Nosocomial transmission from patients with severe acute respiratory distress syndrome to healthcare workers has been reported;⁵ also, many institutions face shortages of personal protective equipment and negative pressure rooms.⁶ Patients with COVID-19 may require aerosol generating procedures (AGP) or therapies (including intubation, extubation, nebulized breathing treatments, non-invasive ventilation [NIV], heated high-flow nasal cannula [HHFNC], tracheostomy, and cardiopulmonary resuscitation). These factors amplify the risks faced by healthcare workers, and are further magnified in low- to middle-income countries, where access to safety equipment may be limited.⁷ Physicians' fear of contracting the virus has been reported to lead to deviations from standard care.⁸

Strategies to mitigate these risks are desperately needed. 'Clinical distancing', a parallel to the practice of social distancing, has been proposed wherein healthcare workers reduce unnecessary contacts with patients to reduce transmission.⁹ Barrier enclosure devices for use during endotracheal intubation have also been proposed,^{10–13} although these have limited broad clinical applicability. Most existing solutions are heavy, rigid, non-disposable (with risk of patient-to-patient transmission), non-adjustable (for differences in proceduralist or patient height or movements), neutral pressure (compared to negative pressure), limited scope (endotracheal intubation only), and limited clinical experience for patients with COVID-19.

In this context, we have developed a system with improvements and unique capabilities in these domains. The novel negative pressure procedural tent (Figure) was developed as a collaborative effort across the University of Michigan and a third-party manufacturer (FlexSys Inc, Ann Arbor, MI). Prototypes made from inexpensive materials have been tested in both healthy volunteers and critically ill patients. Manufacturing, scaling and distribution are being actively pursued. The tent is portable and

allows real-time access to, and manipulation of, the patient. It is designed to provide healthcare workers separation and protection from exhaled droplets and aerosols, while allowing contact and support for procedures. The entire apparatus is disposable and single-patient use, with the exception of the manifold base which can be cleaned and re-used. It is designed to facilitate a range of aerosol-generating procedures (including, but not limited to, intubation, extubation, HHFNC, NIV, nebulized treatments, tracheostomy, bronchoscopy, cardiopulmonary resuscitation with mechanical chest compressions, airway suctioning, oral hygiene, and tracheostomy care). Air exiting the tent passes first through a HEPA filter, drawn out via negative pressure created by an attached vacuum motor, prior to release into room air. Up to 600 air exchanges per hour are generated. This is 50 times greater than the 12 air exchanges per hour recommended by the US Centers for Disease Control and Prevention for negative pressure rooms.¹⁴ It seems feasible that use of the negative pressure tent could help mitigate the need for creation of additional negative pressure rooms (in 2003, this was estimated at \$120,000 per room re-fitted¹⁵).

Air particle testing with the tent was conducted with a healthy volunteer in simulated environments. A TSI Condensation Particle Counter Model 3007 (TSI Inc, Shoreview, MN, USA) was used, which detects particles from 0.01 μm to $>1 \mu\text{m}$. The diameter of the SARS-CoV-2 virus falls within this range (0.06–0.14 μm).¹⁶ Particle counting was conducted with background ambient air, air inside the tent, and air outside the tent at different locations circumferentially around the tent, including at the arm access points and loosely fitting drape. To supplement ambient air particle content in air exhaled from our healthy volunteer, we used a TSI Particle Generator to simulate increased droplet generation and aerosolization associated with a COVID-19 patient.

Throughout testing, particle content of background ambient room air ranged from 100 to 300 particles/cm³. We first maintained our healthy volunteer on HHFNC at 60 L/min with use of the particle generator. Mean air particle content inside the tent was 18,867 particles/cm³; outside the tent, this was 139 particles/cm³. We next maintained our volunteer on HHFNC at 60 L/min, removed the

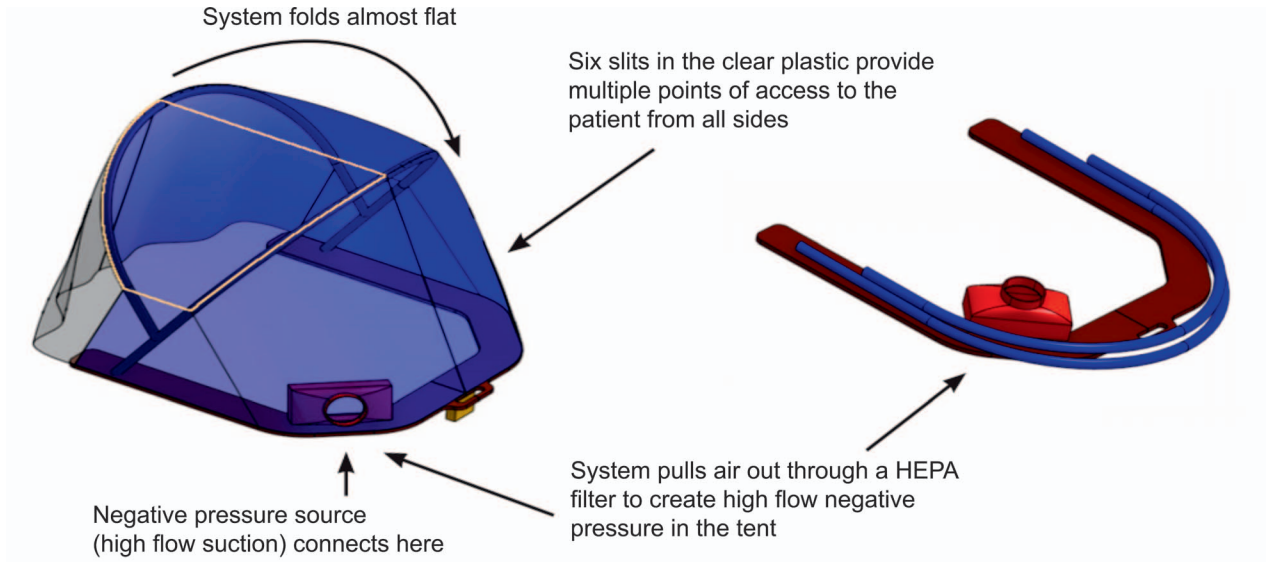


Figure Schematic of the negative pressure procedural tent device. **A)** Patient undergoing tracheostomy in the intensive care unit; **B)** patient undergoing endotracheal intubation in the ED; **C)** patient on non-invasive ventilation undergoing point-of-care ultrasound in the ED; **D)** patient undergoing endoscopic retrograde cholangiopancreatography in procedure suite. Photos used with permission after obtaining informed verbal consent from patients or family members. ED = Emergency Department.

particle generator, and applied a nebulizer mask with saline solution at 10 L/min. Mean air particle content inside the tent was 66,835 particles/cm³, and 338 particles/cm³ outside the tent. We then discontinued HHFNC, and maintained our healthy volunteer on continuous positive airway pressure (CPAP) and deployed the particle generator. Mean air particle content inside the tent was 27,802 particles/cm³, and outside the tent this was 179 particles/cm³.

This simulation included a simulated model of aerosolization with a single healthy volunteer, and our ability to generalize to patients with COVID-19 (or other infections transmitted via respiratory droplets or aerosols) is limited. Nevertheless, these findings suggest a negative pressure procedural tent may allow containment of respiratory droplets and aerosols, while also filtering exhaled air, to avoid exposure for healthcare workers. Use of this device with CPAP, HHFNC, and nebulized treatment was associated with no detectable increase in room air particle counts during testing.

Following pre-clinical testing, we trialed tent prototypes on adult Emergency Department (ED) and Intensive Care Unit (ICU) patients, including with confirmed or suspected COVID-19 (Figure A–D). The tent was well received and garnered positive feedback from physicians, nurses, respiratory therapists, and patients. Use of the tent likely allowed increased safety of healthcare workers during performance of two tracheostomies under sterile conditions, an endotracheal intubation with first pass success, non-invasive ventilation, nebulized breathing treatments, point-of-care ultrasound, and endoscopic retrograde cholangiopancreatography.

Implementation of this novel device has significant potential to benefit patients, healthcare workers and healthcare institutions. Patients with COVID-19 or similar infections may benefit from more liberal use of HHFNC, NIV, or nebulized treatments, with subsequent avoidance or delay of mechanical ventilation. Patients on mechanical ventilation may benefit from earlier liberation from the ventilator via tracheostomy (many current guidelines suggest delaying tracheostomy several weeks until clearance of virus in order to protect proceduralists¹⁷). Healthcare workers could benefit from decreased exposure to respiratory droplets and aerosols from patients with COVID-19 via containment and filtering provided by the tent. Institutions could benefit from a reduced need to create additional negative pressure rooms, safer conditions for proceduralists and surgeons, especially as more elective and semi-urgent procedures are again undertaken, resulting in fewer staff self-isolating, and safer conditions for pre-hospital providers, and intra- and inter-hospital transport.

Benefits and applications of this device are not unique to the United States. Low- to middle-income countries have invested less in healthcare infrastruc-

ture and have an even greater need for inexpensive solutions to benefit patients and healthcare workers. Many infectious diseases besides COVID-19, including influenza and tuberculosis, create similar challenges, and long-term mitigation strategies are needed. The negative pressure procedural tent may create an opportunity for innovation to benefit patients and healthcare workers during the present COVID-19 pandemic, and beyond.

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Conflicts of interest: BSB, NLH, HAP, SK, SSK, and KRW have submitted intellectual property on the device through the University of Michigan, Ann Arbor, MI, USA.

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